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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,592	02/12/2001	Beverly M. Emerson	1211.003US1	1304

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1633

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/781,592

Applicant(s)

EMERSON, BEVERLY M.

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/19/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38,40,54-56,63,64,66,72,74,80-85,88 and 100-105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38,40,54-56,63,64,66,72,74,80-85,88 and 100-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is in response to an amendment filed 5/19/06. Claims 38, 54, 55, 63, 72, 74, 80, 81 and 83 have been amended. Claims 1-37, 39, 41-53, 57-62, 65, 67-71, 73, 75-79, 86, 87 and 89-99 have been cancelled. Claims 100-105 have been added. Claims 38, 40, 54-56, 63, 64, 66, 72, 74, 80-85, 88 and 100-105 are pending in the application.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. The new grounds of rejection herein were necessitated by amendment and, therefore, this action is final.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 63, 64, 66, 68, 73, 74 and 87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 9-12 of copending Application No. 10/783,672. **This rejection is maintained for reasons of record in the office action mailed 2/22/06 and restated below except that the rejection was clarified to cover claims 1-3 and 9-12 as stated in the body of the rejection.**

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in claims 1-3 and 9-12 of US 10/783,672. That is, the cited claims of US 10/783,672 anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, both sets of claims recite a method of identifying a compound that alters chromatin remodeling and that can also be detected by alteration of gene expression. Chromatin assembled DNA is contacted with SWI/SNF complexes and a transcription factor comprising zinc-fingers or leucine zippers.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the U.S. 10/783,672 application, then two different assignees would hold a patent to the claimed invention of U.S. 10/783,672 application, and thus improperly there would be possible harassment by multiple assignees.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument

Applicants have stated that US 10/783,672 only has claims numbered 1-18 and therefore, the heading of the rejection is incorrect in listing claims 69-79 and ask that the rejection be dropped or be clarified. However, the body rejection states that the rejection is over claims 1-3 and 9-12 of US 10/783,672, which has been incorporated into the heading of the rejection.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38, 40, 54-56, 63, 64, 66, 72, 74, 80-85, 88 and 100-105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment.**

The limitation that the peptide "immunoprecipitates with the (a) SWI/SNF chromatin remodeling complex" has been added to claims 38 and 63. Applicant has indicated that support for this limitation is found at pages 5, 19, 20, 22-24, example 2 and original claim 20. These passages teach that chromatin remodeling complexes may be SWI/SNF subunits and state that various DNA binding proteins such as EKLF, Sp1 and GATA-1 cooperate with SWI/SNF to

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remodel chromatin. Far Westerns were used to determine that EKLF interacts with BAF155, BRG1 and BAF170. However, none of these passages teach that the criteria for identifying nucleic acid regulatory protein zinc-finger DNA binding domain peptides is by immunoprecipitation nor that the class of such proteins immunoprecipitates with SWI/SNF. Therefore, the limitation of adding "immunoprecipitates with the (a) SWI/SNF chromatin-remodeling complex" is impermissible NEW MATTER.

The limitation "SWI/SNF chromatin remodeling complex consisting of BRG1 and BAF155" has been added to claims 38. Applicant has indicated that support for this limitation is found at pages 5, 19, 20, 22-24, example 2 and original claim 20. These passages do not teach that a SWI/SNF complex consists of BRG1 and BAF155 alone but rather that the complex consists of BRG1, BAF155, BAF170 as well as other components. The examiner has been unable to find support in the originally filed specification for SWI/SNF chromatin remodeling complexes *consisting* of BRG1 and BAF155 rather the specification teaches that SWI/SNF complexes can be ERC-1 and is comprised of comprise BRG1, BAF170 and BAF155 as well as several other subunits. Therefore, the limitation of adding "SWI/SNF chromatin remodeling complex consisting of BRG1 and BAF155" is impermissible NEW MATTER. It appears that applicants are limiting the subunits used in the screening method to two of the subunits. For accuracy, it would be remedial to recite -- a complex -- rather than "a SWI/SNF" complex".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 38, 40, 54, 63, 64, 66, 72, 74, 80, 83, 84, 87, 88 and 100-105 are rejected under 35 U.S.C. 102(b) as being anticipated by Armstrong et al, Cell, 1998, page 93-104. **This rejection is maintained for reasons of record in the office action mailed and 2/22/06 restated below. Newly added claims 100-105 have been added to the rejection.**

Armstrong et al teach compounds that modulate the binding of EKLF with ERC-1, which comprises several chromatin-remodeling subunits of SWI/SNF (BRG1, BAF170, BAF155). The method involves providing ERC-1, which comprises a subunit of SWI/SNF and EKLF, which is a transcription factor that comprises a zinc-finger DNA binding domain. Additionally, the complex is incubated in the presence of apyrase (see e.g. figure 2). An increase or decrease in chromatin remodeling is assayed by measuring DNaseI sensitivity, which also reflects an increase or decrease in interaction between ERC-1 and EKLF as recited in claim 38, 40, 54, 63, 66, 68, 72, 75-77, 79, 80, 83 and 88. The chromatin is part of β -globin promoter as recited in claim 64. Transcriptional activity can also be monitored (see e.g. figure 3) as recited in claim 87.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 102 on pages 10-13 of the amendment filed 5/19/06. Applicants argue that as Armstrong does not teach a screening method and does not teach that there is a known direct interaction between EKLF and E-RC1. As well, Armstrong doesn't teach use of two subunits BRG1 and BAF155 but teaches use of E-

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RC1 and doesn't teach any zinc-finger DNA binding domain peptide. Thus, Armstrong doesn't teach that a SWI/SNF remodeling complex could remodel chromatin in the presence of less than full-length EKLF and not in the presence of a zinc finger DNA binding domain peptide with which it directly interacts.

Applicants' arguments filed 5/19/06 have been fully considered but they are not persuasive for the following reasons. Armstrong does teach a zinc-finger DNA binding peptide by teaching use of EKLF as there is not size requirement engendered by use of the term "peptide". Rather the transcription factor is a peptide comprising a DNA binding domain. Furthermore, this peptide has inherent activity of binding to SWI/SNF complexes and specifically BRG1 containing complexes and hence will immunoprecipitate with such a complex. Secondly, the method comprises providing a complex consisting of BRG1 and BAF155, which applicants suggest limits the method to those in which the isolated SWI/SNF components BRG1 and BAF155 are alone provided in the method. However, this step a) does not limit the method step to use of only those components. In fact, the claim further recites that a test compound, zinc-finger DNA binding peptides and the SWI/SNF complex are contacted "under conditions" that permit the direct interaction of the complex and zinc-finger peptide. These conditions can include use of the entire SWI/SNF complex. As well, by providing the entire SWI/SNF complex, Armstrong provides BRG1 and BAF155. These components interact with one another and as such are "provided" by Armstrong. Thirdly, the limitation that the DNA binding peptide immunoprecipitates with the SWI/SNF complex is a property of EKLF. As the EKLF of Armstrong shares this property, it does not distinguish the prior art from the instant invention. Finally, applicants' have argued that Armstrong is not drawn to a screening method

and as such does not anticipate the claims. However, the method of Armstrong teaches all of the components of the method of the instant invention and absent evidence to the contrary these steps are all that is required of a screening method. As such, Armstrong anticipates the instant method.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

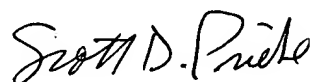
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1633



SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER